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| 10/692,647 | 10/24/2003 | Douglas S. Hine | P10309.00 | 8630 |

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| EXAMINER | |
|---|---|
| ROBERTS, DARIN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3762 | |

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/692,647 | HINE ET AL. | |
| | Examiner | Art Unit | |
| | Darin R. Roberts | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 21-27* is/are rejected.

7)☒ Claim(s) *19,28 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Objections*

**Claims 13 & 14 are objected to** under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 12 expresses the type of lead the lead's deployment the design of the lead as well as the a means for manually guiding said lead, however claims 13 and 14 merely claim a medical lead.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 13,14, 23 & 24 are rejected** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In reference to claims 13, 14, & 24, the applicant mentions a medical lead in the preamble of the claim then fails to further describe the lead.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claims 1-11, 13, 14, 24-27 are rejected** under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In reference to claims 1,13, 14, 24, & 25, these claims are directed toward the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**Claims 1-9 & 11-14 are rejected** under 35 U.S.C. 102(a) as being anticipated by Kroll et al. (US 20020120318 A1).

In reference to ***claim 1***, the Kroll et al. patent teaches the insertion of at least three individual electrodes into one cardiac vein along the epicardial wall as well as a multiple lead system comprising of at least one elongated medical electrical lead and delivery system. Kroll et al. also teaches at least three individually addressable electrodes capable of coupling to three discrete segments of the LV cardiac tissue (see fig. 1 & pp. [0001] & pp. [0036] & pp. [0020]). Kroll et al. also teaches the use of an implantable pulse generator for generating atrial and ventricular stimulation pulses (see pp. [0013]) coupled to the proximal portion of an elongated medical electrical lead (see fig. 1) the Kroll et al. publication also teaches a pulse generator coupled sensing circuitry and impedance measuring circuitry (see pp. [0013]). The Kroll et al. device possesses impedance-measuring leads capable of driving current through tissue and using the sensing circuitry to derive an impedance value (see pp. [0013] & pp. [0017]). Kroll et al. also teaches delivering optimal stimulation therapy (see pp. [0007]) by sampling cardiac signals across any pair of desired electrodes (see pp.58) at least three addressable electrodes (see fig. 1) and in turn applying the appropriate stimulation therapy (see pp. [0060]).

In reference to ***claim 2***, the Kroll patent teaches the use of a defibrillator (see pp. [0026]), and by Kroll's definition, a defibrillator serves to "deliver rhythmic electrical pulses or other anti-arrhythmia therapies to the heart, via electrodes implanted in contact with the heart tissue, at a desired energy and rate" (see pp. [0003]).

In reference to ***claims 3 & 4***, the Kroll patent teaches a device that is "in electrical communication with a patient's heart by way of four leads and suitable for delivering multi-chamber stimulation and shock therapy" (see pp. [0034] and fig. 1), thus it is inherently capable of providing coupled pacing therapy.

In reference to ***claim 5 & 11***, the Kroll patent teaches "... the known uses for an impedance measuring circuit include, but are not limited to, lead impedance surveillance during the acute and chronic phases for detecting proper lead positioning or dislodgement; detecting operable electrodes and conductors; and automatically switching to an operable pair if dislodgement or electrical disruption occurs ..." (see pp. [0067]).

In reference to ***claim 6, 7, 8, & 9***, the Kroll patent teaches the use of at least one mechanical sensor (such as an accelerometer and piezoelectric material) adapted to provide output related to mechanical cardiac performance (see pp. [0065]). Kroll also teaches conveying the output of a mechanical sensor to an implantable pulse generator and a means for sensing cardiac events referred to as an arrhythmia detector (see fig. 3). Kroll also teaches a physiologic sensor commonly referred to as a 'rate-responsive' sensor because it is typically used to adjust pacing stimulation rate according to the exercise state of the patient" (see pp. [0064] & pp. [0065]).

In reference to ***claim 12***, the Kroll patent teaches "lead impedance surveillance during the acute and chronic phases for detecting proper lead positioning or dislodgement; detecting operable electrode and conductors; and automatically switching to an operable pair if dislodgement or electrical disruption occurs (see pp. [0067])" thus

making the leads within the Kroll system "fault-tolerant". Kroll also teaches, "stimulating the left ventricle (via a lead positioned through the coronary sinus with its electrode(s) in a coronary vein overlying the left ventricle) and the right ventricle almost simultaneously ..." (see pp. [0020]). This implies that a means for guiding the distal portion of the lead member into a portion of a coronary sinus thus causing each of said at least three spaced-apart electrodes are disposed in intimate electrical communication with a different discrete volume of cardiac tissue was inherently used (see fig. 1). Kroll also teaches and in electrical communication with a means for addressing each of said at least three spaced-apart electrodes (see fig. 1 & pp. [0062]).

In reference to ***claim 13 & 14***, after inserting the lead into the desired vasculature, the lead will inherently be in contact with discrete volumes of cardiac tissue.

**Claims 23-28 are rejected** under 35 U.S.C. 102(e) as being anticipated by Stadler et al. (US 6795732 B2).

In reference to ***claims 23 & 26***, the Stadler et al. patent teaches a method of reconfiguring electrical communication among at least three electrode pairs coupled to a portion of a reconfigurable medical electrical lead (see fig. 1 & column 10, lines 48-52), said medical electrical lead adapted to couple to a single cardiac chamber, comprising: a) Applying pacing-level electrical stimulation to a portion of myocardial tissue from a single pair of at least three electrode pairs, wherein said at least three electrode pairs

electrically couple to a single elongated medical electrical lead (see fig. 1 & column 10, lines 48-52);

b) Sensing a resulting depolarization wave front between at least two of said at least three electrode pairs (see column 5, lines 12-20).

c) Adjusting a temporal interval parameter based at least in pad on the sensing of the resulting depolarization wave front and repeating step a) and step b) until an acceptable depolarization wave front is sensed (see column 1, lines 54-65), and in the event that no depolarization wave front is sensed, repeating step a) with a different single pair of said at least three electrode pairs (column 24, lead lines 15-34 & column 10, lines 48-53).

In reference to ***claims 24 & 25***, the Stadler et al. patent teaches the use of at least three pairs of electrodes coupled to the anterior surface of the heart (see fig. 1).

In reference to claim 27, Stadler et al. teaches a method comprising of sensing a mechanical property of said myocardial tissue and providing a mechanical output signal related to the mechanical property (see abstract), as well as conveying said mechanical output signal to an implantable pulse generator (see column2, lines 6-13), based at least in part on the mechanical output signal and that the "timing of detected atrial and ventricular sense events is used to ascertain normal sinus rhythm or the presence of bradycardia, tachycardia or tachyarrhythmia in the monitoring and therapy delivery contexts" (see column 2, lines 61-65). Stadler et al. also teaches restarting stimulation with the appropriate timing sequence (see column 2, lines 22-39).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 15-18 are rejected** under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (US 20020120318 A1) in further view of Morgan (US 6094596 A).

In reference to ***claims 15-18***, the Kroll et al. publication teaches at least three electrodes comprises a tip electrode having an axial bore formed through a portion of a tip electrode (see fig. 1 & fig. 4).

The Morgan patent teaches Y-shaped bifurcating electrodes (see fig. 8) that can be advanced into different branches of the middle cardiac vein (see column 7, lines 6-

8), as well as the use of a guide wire through an open lumen to guide the electrode (see column 2, lead lines 39-42).

Thus it would have been obvious to one ordinary skill in the art to combine the aforementioned aspects of the Kroll et al. With the bifurcated lead and guide wire of the Morgan patent to control the spatial distribution of the electrode within the venous system, thereby allowing the electrode to be positioned at a number of desired locations in different vein branches. It would also be obvious to place a guide on the distal tips of the bifurcated lead to guide each tip in the desired direction.

**Claims 10, 21 & 22 are rejected** under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (US 20020120318 A1) in further view of Morgan (US 6094596 A) In further view of Sadler et al. (US 2003/83702 A1).

In reference to ***claims 10, 21 & 22***, the Kroll publication teaches applying pacing-level electrical stimulation to a portion of myocardial tissue from a single pair of multiple electrode pairs (see fig. 1), wherein multiple electrode pairs electrically couple to a single elongated medical electrical lead (see fig. 1). Kroll et al. teaches sensing a resulting depolarization wave front between at least two of said multiple electrode pairs (see abstract) as well as adjusting a temporal interval parameter based at least in pad on the sensing of the resulting depolarization wave front (see abstract). The Kroll publication also teaches mechanical sensor and communication between the sensors and the microcontroller. However Kroll fails to explicitly teach a medium that possesses instructions for sensing mechanical properties of myocardial tissue.

The Stadler et al. publication teaches a lead that possesses at least three pairs of electrodes of electrodes, a microcontroller as well as "RAM memory registers in microcomputer-based control and timing system may be used for storing data compiled from sensed cardiac activity and/or relating to device operating history ..." (see pp. [0064], pp. [0068]). Stadler also teaches repeating step a) and step b) of claim 21 until an acceptable depolarization wave front is sensed', and instructions for repeating step a) with a different single pair of said at least three electrode pairs (see pp. [0124]), and a blood pressure sensor coupled to a pulse generator (see pp. [0005]).

Thus it would have been obvious to one of ordinary skill in the art to combine the aforementioned aspects of the Kroll et al. publication with the memory capabilities of the Stadler et al. publication to review the cardiac history of the wearer as well as provide the device with instruction and commands to follow.

### *Allowable Subject Matter*

**Claims 19, 20, & 28 are objected to** as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Examiner is choosing to cite Kroll et al. (US 6748261 B1)

because it teaches a lead system includes a coronary sinus (CS) lead having a left atrial pacing and sensing electrode and a left ventricular pacing and sensing electrode.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darin R. Roberts whose telephone number is (571) 272-5558. The examiner can normally be reached on 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-9900.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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D. R.

JEFFREY R. JASTRZAB
PRIMARY EXAMINER

2/17/06